INTERSTATE SHIPMENT: From the State of Illinois into the State of Indiana, of a quantity of *sulfathiazole tablets.*

ALLEGED VIOLATION: On or about May 13, 18, and 23, 1949, while the drug was being held for sale after shipment in interstate commerce, the defendants caused various quantities of the drug to be repackaged and sold without a physician's prescription, which acts of the defendants resulted in the drug being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged tablets failed to bear the name and place of business of the manufacturer, packer, or distributor, and a statement of the quantity of the contents; Section 502 (e) (1), a portion of the repackaged tablets failed to bear a label containing the common or usual name of the drug; Section 502 (f) (1), the labeling of the repackaged tablets bore no directions for use; and, Section 502 (f) (2), the labeling of the repackaged tablets bore no warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: June 24, 1950. Pleas of nolo contendere having been entered, the court imposed a fine of $100, plus costs, against the defendants jointly.

3187. Misbranding of Private Formula tablets and Pruvo tablets. U. S. v. 3 Drums, etc. (F. D. C. No. 28008. Sample Nos. 60449–K, 60450–K.)

LIBEL FILED: September 29, 1949, Eastern District of Wisconsin.

ALLEGED SHIPMENT: On or about September 22, 1949, by the Standard Pharmacal Co., from Chicago, Ill.

PRODUCT: 3 drums containing 209,000 *Private Formula tablets*, together with 28 cases, each containing 6 dozen bottles of 75 tablets each, of *Pruvo tablets* at Milwaukee, Wis., in possession of the Pruvo Pharmacal Co. The bottles of *Pruvo tablets*, with each of which was enclosed a circular entitled "Pruvo," had been repacked from 3 drums of *Private Formula tablets* included in the above-mentioned shipment. The bottles were labeled by the consignee, but no written agreement existed between the shipper and the consignee as to labeling such as is contemplated under Section 503 (a) of the Act and the regulations thereunder.

LABEL, IN PART: (Drums) "Private Formula No. P–25,897 Prepared for Wm. SLK Laboratories * * * Each tablet represents: Calcium Succinate 3 gr. Aspirin 4 gr. Caution—to be dispensed only by or on the prescription of a physician * * * This is a bulk shipment intended for repackaging" and (bottle) "Pruvo Acetylsalicylic Acid 4 grains Calcium Succinate 3 grains * * * for Arthritic, Neuritic, Rheumatic Pain Relief."

NATURE OF CHARGE: Misbranding (tablets in drums), Section 502 (f) (1), the labeling of the tablets failed to bear adequate directions for use. The tablets were misbranded when introduced into and while in interstate commerce.

Misbranding (tablets repacked into bottles), Section 502 (a), certain statements on the bottle label and in the circular were false and misleading. The statements represented and suggested that the article was adequate and effective for the treatment and cure of rheumatism and arthritis, whereas the article was not adequate and effective for the treatment and cure of rheumatism and arthritis; and, Section 502 (e) (2), the label of the article

failed to bear the common or usual name of each of its active ingredients since acetylsalicylic acid is not the common or usual name of aspirin. The article was misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: November 21, 1949, and July 14, 1950. The Standard Pharmacal Co., claimant for the 3 drums of the *Private Formula tablets*, and the Pruvo Pharmacal Co., claimant for the 28 cases of *Pruvo tablets*, having consented to the entry of decrees, judgments of condemnation were entered and the court ordered that the tablets be released under bond for relabeling, under the supervision of the Food and Drug Administration.

3188. Misbranding of Fluid Extract No. 118 Celery Fruit (celery seed) and Green's Celery Compound. U. S. v. 10 Bottles, etc. (F. D. C. No. 28463. Sample Nos. 43310–K to 43312–K, incl.)

LIBEL FILED: January 5, 1950, Northern District of Illinois.

ALLEGED SHIPMENT: On or about May 27, July 28, and October 20, 1949, by Eli Lilly & Co., from Indianapolis, Ind.

PRODUCT: 10 1-gallon bottles of *Fluid Extract No. 118 Celery Fruit (celery seed)*, and 10 1-gallon bottles, 106 15-cc. bottles, and 49 30-cc. bottles of *Green's Celery Compound*, at Chicago, Ill., in possession of Green Laboratories (Green Drug Co.), together with various promotional literature.

RESULTS OF INVESTIGATION: The product had been shipped in interstate commerce in gallon bottles under the label "Fluid Extract No. 118 Celery Fruit (celery seed)." A number of the gallon bottles had been relabeled, and some of the product in other gallon bottles had been repacked and relabeled as "Green's Celery Compound" by the consignee, Green Laboratories (Green Drug Co.). The promotional literature, which had been prepared by the consignee, consisted of 10,000 copies each of cards entitled "Attention Users of Green's Celery Compound" and "Why Suffer from Arthritis?" and a leaflet entitled "The Story of Green's Celery Compound," including copies packaged with the 15-cc. and 30-cc. size bottles, and 2,500 posters entitled "Why Suffer From Arthritis?"

LABEL, IN PART: (10 1-gallon bottles labeled when shipped) "Fluid Extract No. 118 Celery Fruit (celery seed) (Apium graveolens) Contains Alcohol 79 percent"; (10 1-gallon bottles and 15-cc. and 30-cc. bottles labeled after receipt in interstate commerce) "Green's Celery Compound Improved * * * Active Ingredient: Apii Fructus, Alcohol 72%."

NATURE OF CHARGE: *Fluid Extract No. 118 Celery Fruit (celery seed)*. Misbranding, Section 502 (f) (1), the labeling failed to bear adequate directions for use since it failed to state the purposes for which the article was to be used and the frequency and duration of administration. The article was misbranded in the above respect when introduced into and while in interstate commerce.

Green's Celery Compound. Misbranding, Section 502 (a), certain statements in the labeling were false and misleading since they represented and suggested that the article was adequate and effective in the treatment of arthritis, rheumatism, lumbago, neuritis, and sciatica, whereas the article was not adequate and effective in the treatment of such conditions. The relabeled article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: July 12, 1950. Default decree of condemnation and destruction.